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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,921	05/06/2002	Graham Paul Luscombe	2544/112	5860
2101	7590	05/11/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			HABTE, KAHSAY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,921

Applicant(s)

LUSCOMBE ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 2-23 are pending.

Response to Amendment

2. Applicant's amendment filed 4/16/04 in response to the previous Office Action (Paper No. 9) is acknowledged. Rejections of claims 1-22 under 35 U.S.C. § 112, second paragraph (Paper No. 9, paragraphs 7a-c) have been obviated. The prior art rejection (item 6) has been maintained. Applicant's amendment also raises new issues that need further rejection.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Note that benzodioxan (A = B = O) and T = phenyl (Group VI) is the elected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerrigan et al. (WO 95/07274). Cited reference teaches the synthesis of benzodioxan

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derivatives for the treatment of drug abuse, drug addiction and eating disorders (see claims 15 and 19-20) are the same as applicants (see Examples 2, 6, 7, 13, 14, 21 etc.). Said species that are used for the treatment drug abuse, drug addiction and eating disorders are the same as applicants, when applicant's formula I has the following substituents:

U = CH₂; Q = NH-CH₂-piperidinyl, piperidinyl-CH₂-NH (see formula IIa), NH-(CH₂)₃-NH (see formula IIb); and T = methoxy-substituted phenyl, chloro-substituted phenyl or phenyl.

Since said derivatives are the same as applicants, a 102(b) rejection is proper.

Note that the only species in claim 19 is also the same as Kerrigan's (see Examples 26-27 or claim 12).

Response to arguments

Applicants' arguments filed 04/16/2004 have been fully considered but they are not persuasive.

Applicants argue that the instant claims are patentable over Kerrigan, since reducing a craving for food or an addictive substance is not the same treatment as the treatment for drug abuse, drug addiction, or an eating disorder. Applicants argue:

"Drug abuse, drug addiction, and eating disorders encompass a broad, generic range of behaviors that may be treated without reducing a craving for food or an addictive

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substance. For example, drug abuse and drug addiction may be treated by mitigating some withdrawal symptoms patients may experience while not regularly taking the drug (e.g., shivering, emotional sensitivity, abnormal body vital signs), though not necessarily affecting the 'craving' for a drug." The examiner disagrees with this conclusion. The treatment of drug abuse or a drug addiction is directly connected with the craving. Treatment of the withdrawal symptoms would not reduce the craving.

Applicants also argue: "In another example, an eating disorder which results in obesity may be treated by accelerating an individual's metabolism, or changing the specific type of food ingested, without any change in the "craving for food" that an individual possesses. In another eating disorder, bulimia, a treatment may reduce the tendency for a patient to induce vomiting, while not necessarily 'reducing the craving for food'.

Furthermore the claimed methods of 'reducing cravings to food or an addictive substance' may be utilized outside the context of treating drug addiction, drug abuse, or an eating disorder. For example, the method may also treat a person who is obese because of an abnormally low metabolic rate by helping to reduce their consumption of food, though the person is not necessarily suffering from an eating disorder. Kerrigan provides a broad generic statement that the compositions revealed may have utility in treating drug addiction, drug abuse, and eating disorders but the reference provides no examples showing the compositions actually treating any of these conditions. Indeed, the only experiments mentioned in Kerrigan refer to assessing the binding interaction of compounds with various receptors of rats (Kerrigan, pages 31 -

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39), and making the various chemical compositions (Kerrigan, pages 40 - 93). Kerrigan provides no specific teaching that the compositions are used as a method for reducing cravings for food or an addictive substance. In contrast, the pending application (see pages 12 - 16) provides specific experiments on rhesus monkeys that support the claimed methods of "reducing cravings to food and addictive substances."

The examiner disagrees with applicant's argument. Kerrigan et al. teaches benzodioxan derivatives that are used for the treatment of drug addiction, drug abuse, (see claim 15) are the same as applicants. Applicants in their own admission indicate that the compositions may have utility in treating drug addiction or drug abuse. Note that craving is the essence of drug addiction. Treating drug addiction or drug abuse necessarily involves reducing the cravings. Since Kerrigan's species are the same as applicants and are used for the treatment of drug addiction or drug abuse, the 102(b) rejection is proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

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a. Regarding claims 21, 20, 13-14, 17-18 and 23 the phrases "includes" or "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Suggested are "having" or "have".

b. In claim 23, the phrase "manufacturing a medicament" is not clear. There is no actual step. This is unduly functional. It recites final product, but not steps or starting material.

c. In claim 23, the phrase "method of producing a substance" is indefinite. What substance is produced? What method produces a substance?

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply for 24 hours, James Wilson (Acting SPE) can be reached at (571)-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

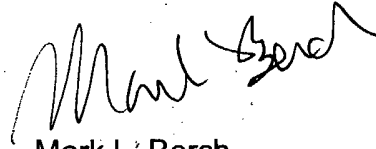
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
May 5, 2004